

REMARKS

Claims 16-18, 28-30, 65 and 66 are currently under examination and have been rejected. Claims 16-18 and 28-30 have been amended. New claims 67-70 have been added.

Information Disclosure Statement

Applicants have filed herewith an Information Disclosure Statement containing references cited in the International Search Report for the parent PCT application, of which the present application is a 371 filing. Applicants have also enclosed a copy of the International Search Report, dated 22 November 2004, which is part of the file in this case.

Claim Rejection Based on 35 U.S.C. 103(a)

Claims 16, 18, 28, 30, 65 and 66 were rejected under 35 U.S.C. 103(a) as being unpatentable over Baak et al. (WO 02/10436, 7 February 2002), which discloses a set of genes expressed differentially in tumors, especially breast cancer, by measuring protein or mRNA (i.e., expression products).

In response, Applicants have amended claims 16 and 28 to recite that the expression is the gene copy number and that the copy number for the test cell (claim 16) or sample (claim 28) is elevated with respect to a normal cell (claim 16) or patient (claim 28), i.e., a cell or patient not otherwise known to be cancerous. The normal cell used in claim 16 or new claim 67 may be from either the same organ or an organ of the same type (such as breast) that is not cancerous. It should be noted that the copy number need not be separately determined for the normal cell or sample in the claimed

method because the copy number for normal cells and samples may already be known to those in the art. To carry out the claimed method, it is only necessary to determine the copy number in test cells or samples and compare that to the value in normal cells and samples of the same type of tissue or organ. This is supported in the application, especially at page 23, lines 12-16, and at page 24, lines 24-31.

The Baak et al. publication does not mention copy number. In addition, copy number is a method much removed from merely measuring elevated expression of a gene, such as by measuring mRNA or protein, since copy number often depends on increased numbers of chromosomes. As a result, it would not have been obvious from the Baak et al. teaching to limit increased gene expression to increase copy number or to correlate such increased copy number with presence of cancer in a patient or the cancerous status of a test cell.

In addition, Applicants have amended claims 17 and 18 (which depend from claim 16) and claims 29 and 30 (which depend from claim 28) to recite that the increased copy numbers are at least 2 fold (claims 17 and 29) or at least 3 fold (claims 18 and 30), respectively. This claim language is supported in the application as filed, especially in Table 3, at page 39, which shows low level amplification of 2 to 3 fold and high level amplification of 3 fold for copy number.

Applicants have also added new claims 67-70. New claims 67 and 69 are drawn to a method of detecting cancer by determining in a test cell or sample the presence of both increased copy number and mRNA for the recited gene. Because both are required, these claims are also patentable over Baak et al., which does not recite measuring increased copy number. These claims are supported in the specification, especially at page 2, line 32, over to page 3, line 3, which discloses that TRIP13 shows both increased copy number and transcription in tumor cells relative to normal cells.

Thus, measuring copy number alone or measuring both copy number and mRNA are each patentable methods over the cited art. New claims 68 and 70 depend from new claims 67 and 69, respectively, and recite that the cell or cancer is breast cell or cancer, respectively. Of course, measurement of copy number and transcriptional expression may be conducted in any order and, for claim 69, on separate samples from the same patient. Copy number and expression level for TRIP13 may be known for normal breast samples and thus need not necessarily be independently determined every time the claimed methods are carried out.

In view of the above amendments and remarks, Applicants believe that this ground of rejection has been overcome and respectfully request that this ground of rejection be withdrawn.

No additional fees are believed due. Applicants request that the Commissioner charge any additional fee for this correspondence, or credit any overpayment, to Deposit Acct. No. 03-0678.

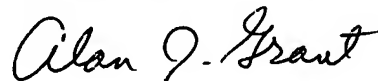
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Alan J. Grant, Esq. 9/1/09
Date

Respectfully submitted,



Alan J. Grant, Esq.
Reg. No. 33,389

CARELLA, BYRNE BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN
5 Becker Farm Road
Roseland, NJ 07068
Phone: 973-994-1700
Fax: 973-994-1744